REMARKS

Claims 1-10 and 27-40, 42-44 and 46-54 are pending in the application with entry of this amendment. Claims 1, 27 and 30 are currently amended. The amendments do not present new matter. Dependent claims 7, 37 and 38 are withdrawn from consideration, and allowance of these claims is respectfully requested upon allowance of a corresponding independent claim.

Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicant acknowledges that the prior rejection of claims under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,755,760 to Maguire *et al.* (hereafter "Maguire") has been withdrawn.

Applicant also acknowledges that the prior rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Maguire in view of U.S. Patent No. 6,063,080 to Nelson has also been withdrawn.

II. Basis of Rejection of Claims 8, 35 and 48 – Nelson or Haissaguerre?

In the previous Amendment, Applicant requested the Examiner to clarify whether the rejection of claims 8, 35 and 48 was based on U.S. Patent No. 6,063,080 to "Haissaguerre" despite the identified patent number identifying "Nelson" as an inventor. No clarifying remarks were provided. Thus, it is Applicant's understanding is that the rejection is based on U.S. Patent No. 6,063,080 to Nelson rather than some other patent to Haissaguerre. Clarification is again respectfully requested if Applicant's understanding is not correct.

III. Claims 1-7, 9-10, 27-34, 36, 39-40, 42-44, 46-47 and 49-54 Are Patentable Over Maguire and Loeb

Independent claims 1, 27, 30 and 47 and respective dependent claims 2-7, 9, 10, 28-29, 31-34, 36, 39-40, 42-44, 46 and 49-54 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Maguire in view of U.S. Patent No. 6,286,512 to Loeb *et al.* ("Loeb"). Applicant respectfully traverses the rejection. Applicant notes that claims 41 and 45 were canceled, and clams 7 is withdrawn from consideration.

A. Maguire fails to disclose the recited combination of coagulation and stimulation elements and associated system components

Maguire fails to disclose, teach or suggest the combination of "a coagulation element configured to emit energy for coagulating tissue and forming a lesion within tissue, the coagulation element defining a coagulation element configuration on the distal region of the relatively short tubular shaft" and "a stimulation element configured to emit energy to tissue for stimulating tissue and evaluating formation of the lesion, the stimulation element defining a stimulation element configuration on the distal region of the same relatively short tubular shaft, the stimulation element configuration being different than the coagulation element configuration" as recited in claims 1, 27 and 30 and the combination of "means for coagulating tissue on the distal region of the relatively short tubular shaft and forming a lesion within tissue" and "means, having a different configuration than the means for coagulating tissue, for stimulating tissue on the distal region of the same relatively short tubular shaft and evaluating formation of the lesion" as recited in claim 47.

It is alleged in the Office Action that the coil electrodes 12 and/or 16 define "a coagulation element configuration," and that the electrode 20 and alternate components define "a stimulation configuration." Office Action (p. 2). However, this is not what is actually described by Maguire since Maguire explains that the electrode 20 is a cardiac mapping electrode. Maguire (col. 3, lines 51-52; col. 4, lines 47-48).

It is known that a cardiac mapping electrode serves as a sensor or antenna for detecting electrical activity of the heart. For example, col. 1, lines 38-50 of U.S. Patent No. 6,063,080 (cited in a prior Office Action) explains that cardiac mapping is used to identify a potential ablation site. This procedure involves inserting a catheter having multiple electrodes into the heart and **monitoring** the electrical signals of the heart in order to identify tissue causing an arrhythmia. In this manner, cardiac mapping electrodes "serve as **individual antennas for detecting** the electrical activity of the heart in the area corresponding to that electrode. As a further example, U.S. Patent Nos. 5,964,753 and 6,360,128 provide other similar descriptions of cardiac mapping procedures and electrodes and explain that cardiac mapping can be used before ablation to locate aberrant conductive pathways within the heart, that aberrant conductive pathways constitute peculiar and life threatening patterns, called dysrhythmias, and that **mapping identifies regions along these pathways, called foci, which are then ablated to treat the dysrhythmia**.

These descriptions of a cardiac mapping electrode and the understanding of persons of ordinary skill in the art as reflected in various other patents have not been addressed or reconciled by the Office Action. Therefore, Applicant has established that other references describe a cardiac mapping electrode as something different than a stimulation element, and that the mapping electrode 20 described by Maguire is not "a stimulation element configured to emit energy for stimulating tissue and evaluating formation of the lesion" as recited in claims 1, 27 and 30. The cardiac mapping electrode 20 does not emit stimulation energy to tissue and does not emit stimulation energy for stimulating tissue. In this regard, the cardiac mapping electrode 20 operates in a manner that is the opposite of a stimulation element that emits energy to tissue to test a lesion resulting from ablation of the tissue. Further, a cardiac mapping electrode 20 as described by Maguire is not "means, … for stimulating tissue on the distal region of the same relatively short tubular shaft and evaluating formation of the lesion" as recited in claim 47.

Moreover, a person of ordinary skill in the art would readily appreciate the differences between a stimulation electrode as recited in Applicant's claims and known mapping electrodes since mapping electrodes are used before ablation of tissue (as explained in U.S. Patent Nos. 5,964,753 and 6,360,128). Therefore, it logically follows that such mapping electrodes are also used before a lesion is formed since a lesion is formed as a result of ablation. Accordingly, based on what is described by U.S. Patent Nos. 5,964,753 and 6,360,128, it is readily understood that a mapping electrode is not a stimulation electrode since mapping electrodes are used before formation of a lesion, and before use of "a stimulation element configured to emit energy to tissue for stimulating tissue and **evaluating formation of the lesion**…"" as recited in claims 1, 27 and 30. Even if a mapping electrode is used after formation of a lesion, the mapping electrode nevertheless operates as a sensor or antenna for receiving and **monitoring** the electrical signals of the heart as opposed to emitting stimulation energy for evaluating formation of a lesion.

B. Sections of Maguire and Loeb cited by the Examiner Do Not Support the Rejection

In the previous Amendment, Applicant requested the Examiner to identify a section of the Maguire that explains that a mapping electrode is a stimulation electrode as recited in Applicant's claims despite the patents identified above referring to a mapping electrode as a sensor and something different than a stimulation electrode. In response, the Examiner appears

to refer to col. 6, lines 1-10 of Maguire and col. 15, lines 51-61 of Loeb. Office Action (p. 3, lines 9-12).

However, with regard to Maguire, it is conceded that "Maguire fails to explicitly disclose a mapping electrode that is a stimulation electrode." Office Action (p. 3). Therefore, it is implicitly conceded that Maguire fails to disclose "a stimulation element configured to emit energy to tissue for stimulating tissue and evaluating formation of the lesion, the stimulation element defining a stimulation element configuration on the distal region of the same relatively short tubular shaft, the stimulation element configuration being different than the coagulation element configuration" as recited in claims 1, 27 and 30, and "means, having a different configuration than the means for coagulating tissue, for stimulating tissue on the distal region of the same relatively short tubular shaft and evaluating formation of the lesion" as recited in claim 47.

The cited section of Maguire refers to a tip electrode 52, and Maguire further explains that the electrode 52 "is employed **primarily for cardiac mapping**." Maguire (col. 4, lines 47-48) (emphasis added). The cited section of Maguire also explains that the tip electrode 52 will be employed "primarily for sensing of cardiac depolarizations and/or delivery of stimulation pulses, rather than ablation, due to its small size." The Office Action, however, does not explain how sensing cardiac depolarization applies to a stimulation electrode that emits stimulation energy for evaluating the formation of a lesion as recited in Applicant's claims. Further, the cited section of Maguire is silent as to a stimulation element configured to emit energy for stimulating tissue and evaluating formation of a lesion. In fact, Maguire does not even refer to and is not related to evaluating formation of a lesion. The Office Action is otherwise silent in this regard consistent with the deficiencies of Maguire.

The cited section of Loeb provides "Such **mapping electrodes** are known in the art and, for example, provide for electrically mapping the heart by receiving and **transmitting** electrical signals related to the operation of that organ **to recording signal processing and display devices**." Loeb (col. 15, lines 51-61) (emphasis added). Thus, contrary to what is alleged in the Office Action, the cited section of Loeb cited by the Examiner actually explains that known mapping electrodes serve as sensors or antennas that receive electrical signals related to operation of the heart. Those received signals are then transmitted to processing and display devices. In other words, based on the cited section of Loeb, the signals that are "transmitted" were received by the mapping electrode and transmitted to processing and display devices.

Stated otherwise, the cited section of Loeb does not disclose a mapping electrode that transmits stimulation energy to heart tissue for evaluating formation of a lesion, then receives electrical signals, and then transmits electrical signals to processing and display devices, particularly considering that it is known that mapping electrodes are sensor devices that do not require stimulation energy to function and instead are sensors, as evidenced by the patents cited above, *e.g.*, U.S. Patent Nos. 5,964,753; 6,063,080 and 6,360,128 discussed above.

Moreover, the cited section of Loeb fails to disclose that such mapping electrodes, which do not even emit stimulation energy to tissue, are configured to evaluate formation of a lesion. The Office Action is understandably silent in this regard consistent with the deficiencies of Loeb.

Thus, the evidence provided by Applicant, and the section of Loeb cited by the Examiner is consistent with the understanding that a stimulation element as recited in claims 1, 27 and 30 and a means for stimulating tissue as recited in claim 47 are fundamentally different than a conventional cardiac mapping electrode. Accordingly, Loeb does not support, and contradicts, the Office Action allegations.

In view of these differences and deficiencies, neither Maguire nor Loeb discloses "a stimulation element configured to emit energy for stimulating tissue and evaluating formation of the lesion, the stimulation element defining a stimulation element configuration on the distal region of the same relatively short tubular shaft, the stimulation element configuration being different than the coagulation element configuration" as recited in claims 1, 27 and 30 and "means, having a different configuration than the means for coagulating tissue, for stimulating tissue on the distal region of the same relatively short tubular shaft and evaluating formation of the lesion" as recited in claim 47.

Accordingly, the misplaced allegations regarding the cited references cannot support the rejection. Allegations to the contrary that rely on the cited references simply disregard certain aspects of various claims:

1. claims 1, 27 and 30 refer to a "stimulation" electrode and not a "mapping electrode" or simply an "electrode";

2. claims 1, 27 and 30 recite that a stimulation element is configured to emit energy to tissue;

3. claims 1, 27 and 30 recite that the stimulation element is configured to evaluate formation of the lesion (which results from tissue ablation by a coagulation element);

4. claim 47 recites means "for stimulating tissue"; and

5. claim 47 recites means "for evaluating the formation of the lesion (which results from tissue ablation by the means for coagulation means)

With regard to Maguire and Loeb, to the extent that it is alleged that a mapping electrode inherently is a stimulation electrode or a means for stimulating tissue as recited in respective claims 1, 27, 30 and 47 (since the references do not actually disclose these elements), Applicant again notes that the Office Action has not satisfied the inherency requirements and cannot support the rejection since the Office Action relies on allegations that are not supported by, and are inconsistent with, what is actually described by Maguire and Loeb and the known manner in which a cardiac mapping electrode 20 operates. MPEP §2112 (to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art; a claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possible present) (emphasis added).

Moreover, to the extent that the Examiner relies on a scientific theory to allege that a mapping electrode is a stimulation electrode or means for stimulating tissue as recited in Applicant's claims, Applicant also notes MPEP §2144.02 (The rationale to support a rejection under 35 U.S.C. § 103(a), may rely on logic and sound scientific principle. *In re Soli*, 317 F.2d 941, 137 USPQ 797 (CCPA 1963). However, when an examiner relies on a scientific theory, evidentiary support for the existence and meaning of that theory must be provided).

Further, in view of general remarks that either do not identify any specific section of a cited reference that allegedly discloses a claim element (*e.g.*, a stimulation element configured to evaluate formation of a lesion), Applicant notes the following: 35 U.S.C. §132 ("Whenever on examination, any claim of a patent is rejected, . . . the Director shall notify the application thereof, stating the reasons for such rejection, . . . together with such information and references

as may be useful in judging of the propriety of continuing the prosecution of his application . . ."); 37 C.F.R. § 1.194(c)(2) ("In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. . . The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.").

C. *Maguire and Loeb do not disclose stimulation energy source and associated components*

As would be expected in view of these differences and deficiencies, it is also conceded that Maguire fails to disclose the combination of "a source of coagulation energy" and "a source of stimulation energy" that is emitted by a stimulation element as recited in claims 27 and 30. Office Action (p. 3, lines 2-3). The Office Action refers to col. 14, line 24 through col. 15, line 18 and Fig. 16. However, the cited section merely refers to an R-F power supply system that is used for ablation.

For example, col. 10, lines 28-55 refer to a R-F power source that is used for ablation electrode(s) (line 48), col. 11, lines 36-60 refer to R-F energy to ablation electrodes, and the cited section (col. 14, line 24 – col. 15, line 18) refers to "yet another embodiment of an RF power supply system" that that R-F outputs are **"provided for individual ablation electrodes** on the catheter, as discussed above." Maguire (col. 14, line 24 – col. 15, line 18) (emphasis added). Thus, the cited section of Maguire does not refer to separate sources of coagulation energy and stimulation energy. Otherwise, the Office Action has not specifically identified a source of coagulation energy and a source of stimulation energy that is used with stimulation electrodes that emit stimulation energy to tissue to evaluate formation of a lesion.

The Office Action is also silent as to "wherein the coagulation energy connector is carried by the handle and the stimulation energy line extends through the handle" as recited in claim 30. The Office Action has not identified any section of Maguire or Loeb that discloses this element of claim 30. 35 U.S.C. §132; 37 C.F.R. § 1.194(c)(2).

In view of these differences and deficiencies, Applicant respectfully submits that Maguire and Loeb, individually and even if somehow properly combined, do not disclose, teach or suggest each element of independent claims 1, 27, 30 and 47. Dependent claims 2-7, 9, 10, 28-29, 31-34, 36, 39-46 and 49-54 incorporate the elements and limitations of respective independent claims 1, 27, 30 and 47 and, therefore, are also believed patentable over the cited references for at least the same reasons. The cited references are also deficient relative to various dependent claims.

For example, the cited references fail to disclose, teach or suggest other claims that recite a "stimulation element" or "stimulation electrode" that is used to evaluate formation of a lesion I view of the above remarks.

Further, Office Action allegations that rely on col. 14, line 24 – col. 15, line 18 and Fig. 16 as disclosing "a source of stimulation energy" as recited in certain dependent claims are also deficient since, as described above, various sections of Maguire refer to a R-F power source that is used for ablation electrode(s), and col. 14, line 24 – col. 15, line 18 refer to "yet another embodiment of an RF power supply system" that that R-F outputs are **"provided for individual ablation electrodes** on the catheter, as discussed above." Maguire (col. 14, line 24 – col. 15, line 18) (emphasis added).

Moreover, claim 5 recites *inter alia* "wherein the stimulation element comprises a stimulation electrode pair." However, the cited electrode 20 is a single electrode separated from other components by an insulation element 18. Maguire (Fig. 1). Further, the electrode 52 is also a single electrode separated from other components by an insulation element 52. Maguire (Fig. 2). Further, the rings 715 described by Loeb are "mapping electrode rings" rather than a pair of stimulation electrodes used for evaluating formation of a lesion.

Accordingly, Applicant respectfully requests that the rejection of claims 1-7, 9-10, 27-34, 39-47 and 49-54 be withdrawn.

IV. Claims 8, 35 and 48 Are Patentable Over Maguire, Loeb and "Nelson"

Dependent claims 8, 35 and 48 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Maguire in view of U.S. Patent No. 6,063,080 to Nelson. As discussed above, page 5 of the Office Action refers to Haissaguerre, but U.S. Patent No. 6,063,080 names Nelson as an inventor, and the Notice of References Cited also refers to Nelson. Thus, it is Applicant's understanding that the Office Action intended to refer to U.S. Patent No. 6,063,080 to Nelson rather than to Haissaguerre.

It is conceded in the Office Action that Maguire fails to disclose at least a portion of a distal region of a relatively short tubular being malleable. Office Action (p. 5). Nelson is cited for the very limited purpose of allegedly disclosing this element with regard to only three dependent claims. Nelson, however, does not cure the substantial deficiencies of Maguire discussed above. Thus, the two cited references, individually and even if somehow properly combined, fail to disclose, teach or suggest each element of claims 1, 8, 27, 35, 47, 48.

Further, Maguire explains that the catheter body 10 that carries ablation and mapping electrodes is a "polymeric" material. Maguire (col. 3, line 45).

Accordingly, Applicant respectfully requests that the rejection of claims 8, 35 and 48 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invites the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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